K120953

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 10 2012

Pleur-evac® Autotransfusion Systems

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8049
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B. Contact Person

Natalie Smith
Regulatory Affairs Specialist

Lorraine DeLong
Manager RA/QE Surgical

C. Date Prepared

March 28, 2012

D. Device Name

Trade Name: Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System, Pleur-evac® Autotransfusion Bag, Pleur-evac® Sahara Autotransfusion Bag

Common Name: Autotransfusion Apparatus

Classification Name: Autotransfusion Apparatus

E. Device Description

Teleflex Medical offers a line of Chest Drainage and Autotransfusion Systems. This line includes Chest Drainage units with a variety of suction and seal technologies. The three lines are the Wet Suction/Wet Seal, Dry Suction/Wet Seal, and Dry Suction/Dry Seal technologies. The Dry Suction/Dry Seal are branded the Sahara Series. Each technology of Chest Drainage devices can be coupled with an Autotransfusion (ATS) Bag for reinfusion capability. In addition, there is the S-1150-08LF, Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System that can be reinfused from the Drainage Unit. This submission will cover the Sahara reinfusion unit and the ATS Bags that can be mated with the different technology Chest Drainage Units.

The Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System (S-1150-08LF) is provided as a sterile unit intended for single patient use. The fluid path is non-

pyrogenic. The Pleur-evac Sahara Plus System is used for the collection and continuous reinfusion of autologous blood. By attaching the Pleur-evac Sahara Autotransfusion Bag (S-100-08LF), the Pleur-evac Sahara Plus System serves as a bag reinfusion system. When autotransfusion is completed, the Pleur-evac Sahara Plus System can serve as a chest drainage collection unit.

The Autotransfusion(ATS) Bag is a sterile, non-pyrogenic, single-use, blood collection and reinfusion device intended for the post-surgical, chest-drainage market. The ATS Bag attaches to the appropriate Pleur-evac® Chest Drainage System. The S-100-08LF attached to a Sahara branded Pleur-evac® unit and an A-1500-08LF attaches to a standard Pleur-evac® unit.

F. Indications for Use
AUTOTRANSFUSION

1. For the collection of autologuous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations

CHEST DRAINAGE

1. To evacuate air and/or fluid from the chest cavity or mediastinum
2. To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum.
3. To help re-establish and maintain normal intra-thoracic pressure gradients.
4. To facilitate complete lung re-expansion to restore normal breathing dynamics.

The Pleur-evac® Autotransfusion Bag is indicated as a sterile, single use device used for collection and reinfusion of autologous blood from the thoracic cavity when attached to a Pleur-evac® System. The fluid path is non-pyrogenic.

G. Contraindications
Pleur-evac® Autotransfusion Systems are contraindicated for:

- Pericardial, mediastinal, or systemic infections
- Pulmonary and respiratory infection or infestation
- Presence of malignant neoplasms
- Coagulopathies
- Suspected thoraco-abdominal injuries with possible enteric contamination
- Impaired renal function
- Intraoperative thoracic or mediastinal cavity use of topical thrombin, microfibrillar hemostatic agents or providine-iodine antiseptic gels or solutions and non I.V. compatible antibiotics

H. Substantial Equivalence

The proposed Pleur-evac® Plus Continuous Autotransfusion System is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Pleur-evac® Sahara Plus Continuous Reinfusion Autotransfusion System	Genzyme Biosurgery	K031554	July 25, 2003
Pleur-evac® Sahara Adult/Sahara Chest Drainage System Models S-1100, S-1200, S-2100 and S-2200 with Model S-100 Autotransfusion Bag	Deknatel DSP Worldwide Incorporated	K962856	September 10, 1996

I. Comparison To Predicate Devices

The proposed Pleur-evac® Autotransfusion Systems have the same technology, indications for use and functional characteristics as the predicate systems. The proposed modification is a change in the material and manufacturing process of the collection tubing of the Pleur-evac Sahara® Plus Continuous Reinfusion Autotransfusion System.

J. Materials

All patient contacting materials are in compliance with ISO10993-1.

K. Technological Characteristics

A comparison of the technological characteristics of the proposed Pleur-evac® Autotransfusion Systems and the predicate has been performed. The results of this comparison demonstrate that the Pleur-evac® Autotransfusion System tubing is equivalent to the marketed predicate devices in performance characteristics. There were no technological changes made to the proposed device.

L. Performance Data

The bench testing has been performed to verify that the performance of the proposed Pleur-evac® Autotransfusion Systems are substantially equivalent to the predicate device, and that the Pleur-evac® Autotransfusion System tubing will perform as intended.

A Summary of the performance testing completed is shown below:

Performance Test	Summary	Result
Kink Resistance	The proposed and predicate patient tubing were visually inspected for kink resistance. This test simulated the various radiuses the tubing could be subjected to during coiling and/or packaging.	The results showed that the proposed patient tubing has a greater ability to withstand kinking.

Performance Test	Summary	Result
Leak Integrity	The proposed tubing was subjected to positive and negative pressures to determine the capability of withstanding leakage.	The proposed tubing passed the leak integrity test with no leaks at tubing joints.
Tubing Clamp Leak	The proposed tubing in a clamped configuration was subjected to positive and negative pressures to determine the capability of withstanding leakage.	The proposed tubing passed the leak test with no leaks at the clamp.
Tubing Collapse	The proposed and predicate patient tubing was exposed to a high amount of negative pressure and visually inspected for tubing collapse.	All units passed the tubing collapse test – the proposed tubing did not collapse under imposed high pressure condition.
ATS Connector Pull Test	The pull test required that the ATS Connector be able to withstand a minimum amount of force without being separated from the proposed tubing.	The proposed tubing withstood the minimum amount of force applied without separation from the ATS Connector.
Back Port Pull Test	The pull test required that the proposed tubing be able to withstand a minimum amount of force without being separated from the Back Port of the unit.	The proposed tubing withstood the minimum amount of force applied without separation from the Back Port.
Universal Connector Pull Test	The pull test required that the Universal Connector be able to withstand a minimum amount of force without being separated from the proposed tubing.	The proposed tubing withstood the minimum amount of force applied without separation from the Universal Connector.

M. Pre-Clinical Testing

The sterilization cycle has been validation to meet the requirements of AAMI/ANSI/ISO 11135-1:2007 Sterilization of health care products Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices, AAMI/ANSI/ISO 11737-1:2006 Sterilization of medical devices – Microbiological methods – Part 1: Determination of the population of microorganisms on product, and AAMI/ANSI/ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.

The Biological Evaluation of the devices met the requirements of AAMI/ANSI/ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing, ISO10993-4 AMD1:2006 Biological Evaluation of Medical Devices – Part

4: Selection of tests in interactions with blood AMENDMENT 1, AAMI/ANSI/ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro cytotoxicity, ISO 10993-10:2002/Amd. 1: 2006 Biological Evaluation of Medical Devices – Pat 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1, AAMI/ANSI/ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity, AAMI/ANSI/ISO 10993-12 :2007 Biological Evaluation of Medical Devices – Part 12 Sample preparation and reference materials, AAMI ST72:2002/(R)2010 Bacterial endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing, ASTM F-2382-04:2009 Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT), ASTM F-756-08:2009 Guideline, Standard Practice for Assessment of Hemolytic Properties of Materials, ASTM F2148-07:2007 Standard Practice for Evaluation of Delayed Contact Hypersensitivity using the Murine Local Lymph Node Assay (LLNA) and United States Pharmacopeia 35, National Formulary 30, 2012. <151> Pyrogen Test.

The packaging and shelf life has been validated to meet the requirements of AAMI/ANSI/ISO 11607-1:2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems, AAMI/ANSI/ISO 11607-2:2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes, ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices, ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems, ASTM D999:2008 Standard Test Methods for Vibration Testing of Shipping Containers, and ASTM D5276 Standard Test Method for Drop Test for Loaded Containers by Free Fall.

N. Summary of Letter to File Modifications

Additional modifications were made to the device since the last clearance. These modifications and a summary of the performance testing are shown below:

Device Modification	Description of Modification	Summary of Performance Testing
Material Change: Autotransfusion Bag – Top Plate	The design of the Autotransfusion Bag includes a rigid PVC top plate assembled onto the top of a vinyl, flexible bag. The rigid PVC was composed of a copolymer and the manufacturer discontinued the resin. The replacement material (resin) was a homopolymer that was one of the components of the copolymer.	Performance testing was completed to assess the Radio Frequency weld strength, Pressure/Decay, Tensile, Burst and Stress. All testing passed minimum requirements. All biocompatibility testing was completed according to ISO 10993-1 and USP <181>.

Device Modification	Description of Modification	Summary of Performance Testing
Material Change: Auto transfusion Bag – IV Strap	The hanger strap material was changed due to supplier material obsolesces. This is a non-patient contacting material.	The change to the top plate was validated through a validation study to ensure that the IV strap material met visual acceptance criteria after aging.
Supplier Process Change: Header Bags sterile barrier for transportation	Sealing of the header bags changed from an impulse sealer to a hot bar sealer. This is a non-patient contacting process change.	The study investigated three packaging criteria, seal strength, seal width, and seal visual defects that are outlined in Purchasing Specification. All pre-established specifications were met.
Modification: Replacement of Sterile Water Bottle with Sterile Water Syringe	Changed water delivery from a bottle of sterile water to a syringe. This is a non-patient contacting material.	The component change was validated through design verification activities where four different tests (ship testing, syringe position, tip cover attachment, syringe leakage) were performed to assure safety and performance. To ensure that the prefilled syringe was not negatively impacted by Ethylene Oxide (EtO) a study was performed to measure the amounts of EtO and Ethylene Chlorohydrin after the syringe was sterilized twice. All results passed.
New Mold: Swabbable Stem (ATS Connector component)	New mold for swabbable stem component which results in dimensional changes. The patient contacting material and function of the component was unchanged.	The functional tests performed include leak testing and needles injection after the swabbable stem was assembled within the ATS connector assembly. A dimensional inspection of swabbable stems was also performed to determine whether the new components produced by the mold met drawing dimensions. All results passed.

Device Modification	Description of Modification	Summary of Performance Testing
Modification: Male ATS Connector	Change in component design. The patient contacting material and function of the component was unchanged.	The functional tests included finger engagement, disengagement force, Male ATS connector disengagement clearance and ATS connector separation force. A dimensional inspection was also performed to determine whether the new components produced by the mold met drawing dimensions. All results passed.
Mold Location and Manufacturer Change: Air Flow Meter	Mold location change due to cost savings efforts to consolidate molding supplier. This is a non-patient contacting component.	The functional tests included correct flow path, no leaks through front of air flow meter and air flow measurement. A dimensional inspection was performed to determine whether the new components produced by the mold met drawing dimensions. All results passed.
Material and Mold Location Change: Slide Clamp	Mold location change due to cost savings efforts to consolidate molding supplier. Material change due to supplier material obsolesces. This is a non-patient contacting component.	The design verification activities included dimensional inspection on all mold cavities and functional testing to determine if the tubing leaked while clamped. All results passed.
Mold Location Change: Hanger	Mold location change due to cost savings efforts to consolidate molding supplier. This is a non-patient contacting component.	Functional testing consisted of verifying hanger fit and form, and hanger strength. Dimensional measurements were executed as part of a first article inspection. All results passed.
Mold Location Change: Swivel Arm	Mold location change due to cost savings efforts to consolidate molding supplier. This is a non-patient contacting component.	Functional testing consisted of verifying swivel arm deflection, lock override, removal force, actuation force and rotational resistance. Dimensional measurements were executed as part of a first article inspection and critical dimension study. All results passed.
Material Change: Swivel Arm	Mold location change due to cost savings efforts to consolidate molding supplier. This is a non-patient contacting component.	Functional testing consisted of verifying swivel arm deflection, lock override, removal force, actuation force and rotational resistance. Dimensional measurements were executed as part of a first article inspection and critical dimension study. All results passed.

O. Conclusion

Based upon the comparative test results, the proposed Pleur-evac® Autotransfusion Systems are substantially equivalent in performance to the predicate devices cleared to market via 510(k) K031554 and K962856. The modifications made to the proposed Pleur-evac® Autotransfusion Systems do not introduce any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 10 2012

Teleflex Medical, Inc.
C/O Ms. Lorraine DeLong
2917 Weck Drive,
Research Triangle Park, NC 27709

Re: K120953
Trade/Device Name: Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: December 4, 2012
Received: December 4, 2012

Dear Ms. DeLong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Digitally signed by Bram D. Zuckerman
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Bram D. Zuckerman, 0.9.2342.19200300.100.1.1=1300079955
Date: 2012.12.10 16:29:52 -05'00'

Bram D. Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120953

Device Name: Pleur-evac® Autotransfusion Systems

Indications for Use:

The Indications for Use Statements are as follows:

AUTOTRANSFUSION

1. For the collection of autologuous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post-operative situations

CHEST DRAINAGE

1. To evacuate air and/or fluid from the chest cavity or mediastinum
2. To help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum.
3. To help re-establish and maintain normal intra-thoracic pressure gradients.
4. To facilitate complete lung re-expansion to restore normal breathing dynamics.

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Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120953